

The present invention may be further understood from the following examples:

#### EXAMPLE 1

Fresh calfskin (about 5 kg.) was dehaired, cleaned by shaving and cut into small pieces. The skin was solubilized in 10 liters of water (pH 2.5, HCl) by addition of 1 g of pepsin (approximate ratio of enzyme to collagen is 1/400) and kept at 20° C. for five days with intermittent stirring. The resulting viscous solubilized collagen was filtered through cheesecloth, its pH adjusted to 10 by NaOH and allowed to stand for 24 hours at 4° C. to inactivate the pepsin. The pH of collagen was then adjusted to 7 to 8 (HCl) and collagen precipitate was collected by centrifuging. Fatty constituents were then removed from the collagen. To one part of collected collagen was added two parts of fat solvent, e.g., ethanol-ethyl ether mixture (1:1) and the mixture was homogenized in a Waring blender. Collagen was separated from solvent by squeezing in cheesecloth and homogenized again with the same volume of solvent. After being squeezed it was air-dried to remove solvent and redissolved in acidified water (pH about 3.0) to make collagen gel.

On the lower concave part of a lower lens mold (glass) was placed 0.2 g of 5% clear collagen gel and centrifuged for 30 minutes at 3000 rpm at 10° C. to make the collagen gel spread evenly across the mold surface. After 10 minutes evacuation in vacuum, the upper convex part of the lens was pushed onto the lower mold containing the collagen gel and the entire mold transferred to an irradiation vessel. The vessel was flushed and filled with nitrogen and gamma-irradiated for 10 hours at a dose rate of 82 K rads per hour. The molded collagen lens was neutralized by phosphate-saline buffer, (pH 7.2) and transferred to normal saline. The lens was placed on the convex part of a teflon mold, frozen and trephined while the lens was frozen. The finished lens was kept in normal saline solution. This lens is optically clear, flexible and stable, and displays excellent properties as a soft contact lens.

The irradiation was carried out in a Gammator M type gamma irradiator obtained from Radiation Machinery Corporation, Parsippany, New Jersey and such irradiation equipment is not part of the inventive subject matter hereunder. The glass vessel containing the lens mold during irradiation was a standard, relatively wide-mouth, two-hole rubber-stopped vessel permitting removal of air and filling with nitrogen.

The lens molds (which likewise do not form part of this invention), were manufactured from brass, glass and plastic. The mold consists of a lower concave part and an upper convex part. The surface of the convex part, when the mold is closed, reaches the surface of the concave section, except for the desired thickness of the collagen lens. The desired thickness is approximately 0.4 millimeters, preferably about 0.3 millimeters. Most lens material was finished with a trephine (cylindrical instrument with one razor-sharp circular cutting end), to a tapered edge lens. Instead of trephining, however, a lathe operation may also be used to finish the lens material.

#### EXAMPLE 2

A soft lens was prepared by a procedure similar to Example 1 except 12% collagen gel, a stainless steel mold and irradiation time of 20 hours were substituted. Again the resulting lens was optically clear, flexible and

stable, and displayed excellent properties as a soft contact lens.

#### EXAMPLE 3

Stabilized, defatted collagen prepared in Example 1 was succinylated by the following procedure: Five grams of collagen were solubilized in 2 liters of acidified water (pH 3.0, HCl) and the pH thereafter adjusted to 9.0 by NaOH solution. Acetone solution (100 ml) containing 2 g succinic anhydride was gradually added to the collagen suspension. During the addition of succinic anhydride the pH of collagen suspension was maintained at about 9.0 by NaOH solution. Succinylated collagen was precipitated by acidification to about pH 4.2, washed repeatedly with water and freeze-dried. Transparent 2.5% succinylated collagen gel of pH 7 was placed on the lower mold part (brass) indicated and processed in the same way as Example 1 except that 8 hours irradiation was employed. The resulting lens was completely transparent, pliable, and sufficiently strong to function as a soft contact lens. It is very comfortable to wear.

All of the lenses prepared above are susceptible of modification to prescription values by known optical techniques. Thus, soft contact collagen lenses can be prepared for use by patients requiring known normal sight corrective measures, e.g., incorporation of spherical power.

The advantages of soft lens made from solubilized collagen from a medical standpoint are summarized as follows:

1. Successful implantation of a material into the corneal stroma requires that the material be inert and highly permeable to water, nutrients, oxygen and carbon dioxide. To date collagen is the only material used for contact lenses that can be so implanted without subsequent rejection. All other materials used for contact lenses are extruded when implanted in the cornea.

2. The collagen/water ratio of the cornea and the collagen contact lens are strikingly similar. These two materials are closely related structurally, physiologically and immunologically. All other contact lens materials are totally unrelated to the collagen protein of the cornea.

The advantages from the consumer of wearer standpoint are summarized as follows:

1. The gas and water vapor permeability of the collagen membrane make it ideally suited for a constant wear contact lens without disrupting essential metabolic pressures in the cornea.

2. The similarity of this protein and the principal protein of the cornea make allergic and toxic reactions between the two very unlikely.

3. The low cost of preparation of the collagen lens material indicates a low cost to the consumer.

4. Collagen contact lenses are soft, pliable and transparent. Spherical power can be incorporated into them.

Having described the invention in the above detail, what is claimed is:

1. As an article of manufacture a soft contact lens consisting of a lens-shaped, subsequently cross-linked gel of solubilized, defatted, collagen, said gel comprising 1.0 to 30.0 wt. % collagen and the balance water.

2. A soft contact lens of claim 1 in which the lens-shaped collagen gel is chemically cross-linked.

3. As an article of manufacture a soft contact lens consisting of a lens-shaped, subsequently cross-linked